

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware
Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited
Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

SECOND AMENDED COMPLAINT FOR:

- 1. INFRINGEMENT OF UNITED STATES PATENT NO. 8,926,490**
- 2. INFRINGEMENT OF UNITED STATES PATENT NO. 10,029,111**
- 3. INFRINGEMENT OF UNITED STATES PATENT NO. 8,465,408**
- 4. INFRINGEMENT OF UNITED STATES PATENT NO. 8,870,737**

DEMAND FOR JURY TRIAL

SECOND AMENDED COMPLAINT

Plaintiff Wave Neuroscience, Inc. (“Wave” or “Plaintiff”) complains and alleges as follows against defendant Brain Frequency, LLC (“Brain Frequency” or “Defendant”):

NATURE OF ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Wave seeks damages, attorney’s fees, costs, pre and post-judgment interest, and permanent injunctive relief.

THE PARTIES

2. Wave Neuroscience is a Delaware corporation with a principal place of business at 1601 Dove Street, Suite 205, Newport Beach, California 92660.

3. Brain Frequency is a Texas limited liability company with a principal place of business at 26229 North Cranes Mill Road, New Braunfels, TX 78133.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Brain Frequency because: (a) Brain Frequency's principal place of business is in this District; (b) Brain Frequency transacts business in and maintains continuous and systematic contacts with this District and the State of Texas; and (c) Brain Frequency has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in this District and elsewhere in Texas and the United States.

6. Venue is proper in the United States District Court for the Western District of Texas under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Defendant resides in, has committed acts of patent infringement in, and has regular and established places of business in this District.

7. Certain products manufactured by or for Brain Frequency and/or infringing services have been and/or are currently being offered for sale by Brain Frequency operating out of its principal place of business in this District. Those products and services are being offered within this District and other locations within Texas and throughout the United States.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS FOR RELIEF

Wave Neuroscience's Business

8. Wave is a recognized global-leader in developing personalized, non-invasive technology aimed at addressing neurological disorders and enhancing cognitive brain function through Transcranial Magnetic Stimulation ("TMS").

9. Wave’s technological advancements in the areas of testing and treatment of neurological disorders and in enhancing cognitive brain function using TMS are evidenced by its extensive patent and trademark portfolio and its collection of proprietary historical data of patient electroencephalogram (“EEG”) results and associated medical conditions.

10. Wave’s patented technology involves analyzing patients’ EEG results to derive insight into the patients’ brain health. Wave combines its proprietary algorithms with years of proprietary historical data to create an actionable cognitive treatment report. Doctors and clinics use Wave’s patented equipment and treatment protocols to treat patients to achieve long-lasting cognitive health.

11. NeoSync, Inc. (“NeoSync”) was founded in 2008 as a clinical stage company. NeoSync helped pioneer personalized TMS for the treatment of major depressive disorder and other diseases of the central nervous system. Medical professionals acknowledged the synchronized transcranial magnetic stimulation using EEG was a “new neuromodulation technique,” and confirmed the findings using NeoSync’s EEG Synchronized TMS (“N.E.S.T.”) device.¹

12. On February 13, 2020, Wave acquired certain assets from NeoSync, including, but not limited to two of the patents at issue in this case, which enhanced Wave’s patent and trademark portfolio, along with its collection of proprietary historical data of patient EEG results and associated medical conditions.

13. Kosivana Holdings Limited (“Kosivana”) was founded in 2015 as a location in Cyprus for Wave Neuroscience, which was then doing business as Newport Brain Research

¹ Cook I.A., Wilson A.C., Corlier J., Leuchter A.F. 2019. Brain Activity and Clinical Outcomes in Adults With Depression Treated With Synchronized Transcranial Magnetic Stimulation: An Exploratory Study. *Neuromodulation* 2019; 22: 894–897, attached as Exhibit 6.

Laboratory, Inc (“Newport Brain Research Laboratory”). Kosivana helped develop technologies relating to rTMS devices and the treatment of pain, mental disorders, and spinal disorders.

14. On June 12, 2019, Wave acquired certain assets from Kosivana, including, but not limited to, one of the patents at issue in this case, which enhanced Wave’s patent and trademark portfolio related to its proprietary TMS and rTMS products.

15. Wave is currently conducting an FDA-grade clinical study, Phase I of which was funded by the U.S. Department of Defense to validate the safety and medical efficacy of its proprietary technology for the treatment of persistent post-concussion symptoms and persistent post-concussive syndrome from traumatic brain injury in collaboration with U.S. Special Operations Command. Phase II will proceed with funding from the Texas A&M Institute for Bioscience and Technology.

16. Wave’s patented technology is being used by or in connection with its numerous strategic partners including, but not limited to, the U.S. Department of Defense, Department of Veterans Affairs, Special Operations Care – Fund (SOC-F), Tomahawk Charitable Solutions, Texas A&M Institute for Bioscience and Technology, Ohio State University – Physical Medicine and Rehabilitation, Kerlan-Jobe Orthopedic Sports Medicine, Cedar-Sinai, University of Southern California Center for Neurorestoration, Enterhealth Ranch - Substance Abuse Treatment Center, and Warriors Heart – Addiction, Chemical Dependency & PTSD Treatment Center for Active Military, Veterans, and First Responders.

17. Wave’s products, services, and successful treatments have been featured on over 50 podcasts including The Broken Brain, Finding Center, The Joe Rogan Experience, Bulletproof Veteran, Military Veteran Dad, Vets First, and many more.

18. With the assistance of Veteran Service Organizations and various non-profit organizations, Wave has underwritten more than \$1 million in care for Veterans in need.

The Asserted Patents

19. Mental disorders generate serious problems for those who suffer from them, their families, and society. Historically, physicians have treated these disorders with a variety of medications, many of which have significant negative side effects. Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-pharmaceutical procedure utilizing an electromagnet placed on the scalp that generates a series of magnetic field pulses roughly the strength of an MRI scan.

20. Patients receiving treatment for persistent post-concussion symptoms due to Traumatic Brain Injury² and depression symptoms (PHQ9) using Wave's proprietary technology have demonstrated promising results with robust academic rigor sufficient to warrant prestigious grant and research funding in excess of \$15 million.

21. Wave has developed or acquired numerous patents that implement its rTMS treatments. These patents cover specific methods of treatment for specific patients using a specific administration of frequencies at specific conditions to achieve a specific outcome.

22. On January 6, 2015, the U.S. Patent and Trademark Office issued United States Patent No. 8,926,490, entitled "SYSTEMS AND METHODS FOR DEPRESSION TREATMENT USING NEURO-EEG SYNCHRONIZATION THERAPY" (the "'490 Patent"). A true and correct copy of the '490 Patent is attached as Exhibit 1.

23. The '490 Patent describes systems for a novel, inexpensive, and easy to use therapy for treatment of depression using alternating magnetic fields to gently "tune" the brain and affect symptoms of depression.

² Based on the Rivermead Post-Concussion Questionnaire 16 ("RPQ16").

24. On July 24, 2018, the U.S. Patent and Trademark Office issued United States Patent No. 10,029,111, entitled “RTMS AT HARMONICS OF BIOLOGICAL SIGNALS” (the “’111 Patent”). A true and correct copy of the ’111 Patent is attached as Exhibit 2.

25. The ’111 Patent describes methods of administration of rTMS at a pulse rate equal to, or a harmonic of, a patient’s given biological metric, such as heart rate or respiratory rate, to establish frequency coupling among different organs through rhythmic entrainment using the harmonic closest to the desired EEG frequency based on the targeted cognitive element or symptom.

26. On June 18, 2013, the U.S. Patent and Trademark Office issued United States Patent No. 8,465,408, entitled “SYSTEMS AND METHODS FOR MODULATING THE ELECTRICAL ACTIVITY OF A BRAIN USING NEURO-EEG SYNCHRONIZATION THERAPY” (the “’408 Patent”). A true and correct copy of the ’408 Patent is attached as Exhibit 3.

27. The ’408 Patent describes methods, devices, and systems for a novel, inexpensive, easy to use therapy for treatment of coma, post-traumatic stress disorder, Parkinson’s disease, cognitive performance, and/or amblyopia that gently “tune” the brain and affect symptoms thereof.

28. On October 28, 2014, the U.S. Patent and Trademark Office issued United States Patent No. 8,870,737, entitled “SYSTEMS AND METHODS FOR NEURO-EEG SYNCHRONIZATION THERAPY” (the “’737 Patent”). A true and correct copy of the ’737 Patent is attached at Exhibit 4.

29. The ’737 Patent describes methods, devices, and systems for a novel, inexpensive, easy to use therapy for a number of disorders. The methods and devices described use alternating magnetic fields to gently “tune” the brain and affect mood, focus, and cognition of subjects.

30. The '490 Patent, '111 Patent, '408 Patent, and '737 Patent are referred to collectively as the "Asserted Patents."

31. Wave's products and services are acknowledged as being breakthrough treatments, new and novel for improving brain health and clinical results for treatment of many disorders. The tremendous success of Wave's treatments, including its patented devices and methods, confirms that the inventions claimed in the Asserted Patents were not well-understood, routine, or conventional at the time of the Asserted Patent's filings. To the contrary, the claimed devices, systems, and methods have solved technical problems to provide unique solutions for patient brain health and treating specific conditions. Some exemplary publications illustrating Wave's commercial success and unique solutions to brain health include:

Business Wire³

Infinite Hero Foundation⁴

Football Morning In America⁵

Autism Parenting⁶

Defense One⁷

Local10⁸

³ <https://www.businesswire.com/news/home/20190904005867/en/Special-Operations-Care-Fund-SOC-F-and-Tomahawk-Charitable-Solutions-to-Support-Leader-in-Neurotherapeutics-to-Provide-Breakthrough-Treatment-Technology-for-Special-Operations-Veterans> attached as Exhibit 7.

⁴ <https://www.prnewswire.com/news-releases/infinite-hero-foundation-announces-2014-grants-281743191.html> attached as Exhibit 8.

⁵ <http://profootballtalk.nbcsports.com/2019/06/10/fmia-guest-nick-hardwick-post-nfl-brain-health/> attached as Exhibit 9.

⁶ <https://www.autismparentingmagazine.com/autism-mert-therapy/> attached as Exhibit 10.

⁷ <https://www.defenseone.com/technology/2019/01/zap-how-electric-therapy-curing-navy-seals-ptsd-and-could-remake-brain-science/154301/> attached as Exhibit 11.

⁸ <https://www.local10.com/health/2020/01/30/brain-treatment-center-offers-novel-approach-to-treat-autism/> attached as Exhibit 12.

32. The success of Wave’s patented technology is also reflected in the fact that Wave not only has more than thirty licensed clinics performing treatments daily in California, Florida, Colorado, Maryland, Nevada, New York, Oklahoma, Texas, and Virginia, but also operates clinics internationally in Panama and Australia.

INFRINGING CONDUCT

33. The tremendous popularity and commercial success of Wave’s patented technology has spawned imitators, including Brain Frequency, which has and continues to copy Wave’s products and services. Defendant is actively—directly and indirectly—infringing the Asserted Patents.

34. According to Defendant’s website, Brain Frequency founder and member Shannon Malish, a licensed social worker, developed Brain Frequency’s infringing treatment methods and oversees their use.⁹

35. Brain Frequency actively promotes the commercial development of Brain Frequency’s technology and methods.¹⁰ The equipment used in Brain Frequency’s treatments is regulated by the FDA according to Brain Frequency’s website.¹¹

36. “The Brain Frequency™ system” induces neuromodulation after performing an EEG to measure electrical patterns in the brain. The Brain Frequency system then uses “gentle, short, magnetic pulses” to treat symptoms like depression and anxiety. This description, among many other examples on Defendant’s public website and YouTube channel,¹² confirms Defendant’s products and services directly infringe the Asserted Patents.

⁹ See, e.g., Gladden Longevity Podcast, Nov. 2022, “Is this how you fix your brain once and for all?” (in which Ms. Malish explains the development of and treatment of patients using Brain Frequency’s techniques) (available at <https://gladdenlongevitypodcast.com/episodes>, and <https://gladdenlongevitypodcast.com/episodes/f/is-this-how-you-fix-your-brain-once-and-for-all> and <https://open.spotify.com/episode/1tYFdD61I7dN4nvD7YrKKK?si=ef34fadb30054a80>)

¹⁰ See *id.* (Gladden Longevity Podcast)

¹¹ <https://brainfrequency.ai/treatment-process>

¹² <https://www.youtube.com/@BrainFrequencyai>;

37. Brain Frequency's treatment procedure is used at numerous "Brain Frequency™ Locations," including Gladden Longevity in Texas, Live In Alignment in California, BioMed Scottsdale in Arizona, and Energy4Life Centers in Utah.¹³

38. On information and belief, Brain Frequency does not perform medical activities or administer patient treatments. Instead, Brain Frequency was formed to develop technology and to commercialize that technology by licensing it to third-party medical providers to treat their own patients. As a result, Brain Frequency is not a "related health care entity" as that term is defined in 35 U.S.C. § 287(c).

39. The '490 Patent describes, among other things, a system of treating depression using a magnetic field generator with a non-transitory computer readable medium containing a particular data value and a processor configured to control the magnetic field based on that data value according to specified parameters to increase or decrease blood flow in particular regions of the brain. Exhibit 1 ('490 Patent) Claim 1.

40. Disclosures made on Defendant's website shows the infringement of each element of Claims 1, 8, and 9 of the '490 Patent, which is presented in Exhibit 5.

41. The '111 Patent describes, among other things, a method of improving a physiological or neuropsychiatric condition by subjecting a patient to rTMS at a frequency, or a harmonic or sub-harmonic, of a non-EEG biological metric. Exhibit 2 ('111 Patent) Claim 1.

42. Disclosures made on Defendant's website showing infringement of each element of Claims 1-7 of the '111 Patent, which are presented in Exhibit 5.

43. The '408 Patent describes, among other things, a method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder, treating amblyopia, and/or enhancing cognitive performance in a subject by moving an intrinsic frequency of a brain of the

¹³ <https://brainfrequency.ai/texas>

subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band, by applying a magnetic field close to a head of the subject, wherein the magnetic field comprises the intrinsic frequency of the brain of the subject within the specified EEG band. Exhibit 3 ('408 Patent) Claim 2.

44. Disclosures made on Defendant's website shows the infringement of each element of Claims 1-4, 9-12, and 20-21 of the '408 Patent, which are presented in Exhibit 5.

45. The 8,870,737 Patent describes, among other things, a method comprising: adjusting output of a magnetic field, applying said magnetic field close to a head of a subject, and moving, using the magnetic field, an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band, wherein the preselected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject. Exhibit 4 ('737 Patent), Claim 2.

46. Disclosures made on Defendant's website shows the infringement of each element of Claims 1-4, and 8-11 of the '737 Patent, which are presented in Exhibit 5.

47. Defendant has had actual knowledge of the existence of the '490 and '111 Patents since at least as early as the receipt of the letter dated May 15, 2023, that accompanied the original Complaint filed in this action.

COUNT I

INFRINGEMENT OF UNITED STATES PATENT NO. 8,926,490

48. Wave incorporates the allegations of paragraphs 1-47 as if set forth here.

49. On January 6, 2015, the U.S. Patent and Trademark Office duly and legally issued the '490 Patent.

50. At all relevant times, Wave or its predecessor-in-interest, NeoSync, has been the lawful owner of right, title, and interest in and to the '490 Patent, including the right to sue for and collect past damages.

51. The '490 Patent is valid and enforceable.

52. As demonstrated by the claim chart attached as Exhibit 5, Defendant has been and is directly infringing pursuant 35 U.S.C. § 271, literally or under the doctrine of equivalents, one or more claims of the '490 Patent, including Claims 1, 8, and 9 of the '490 Patent by making, using, manufacturing, importing, offering for sale, and/or selling systems that incorporate the system claimed in the '490 Patent.

53. As demonstrated by the claim chart attached as Exhibit 5, Defendant has also been inducing, and continues to induce its customers pursuant to 35 U.S.C. § 271 to directly infringe one or more claims of the '490 Patent, including Claims 1, 8, and 9 of the '490 Patent, by intentionally promoting, aiding, and instructing customers to purchase and use systems that incorporate the system claimed in the '490 Patent.

54. Defendant knew or should have known the purchase and use of systems that incorporate the systems claimed in the '490 Patent by its customers directly infringes one or more claims of the '490 Patent, including Claim 1 of the '490 Patent. Direct infringement by Defendant's customers is evidenced by statements on its customers' websites, for example, as shown in the claim charts attached to this Second Amended Complaint.

COUNT II

INFRINGEMENT OF UNITED STATES PATENT NO. 10,029,111

55. Wave incorporates the allegations of paragraphs 1-47 as if set forth here.

56. On July 24, 2018, the U.S. Patent and Trademark Office duly and legally issued the '111 Patent.

57. At all relevant times, Wave, its predecessor-in-interest, Kosivana, or its predecessor in interest, Newport Brain Research Laboratory, has been the lawful owner of right, title, and interest in and to the '111 Patent, including the right to sue for and collect past damages.

58. The '111 Patent is valid and enforceable.

59. As demonstrated by the claim chart attached as Exhibit 5, Defendant has also been inducing, and continues to induce, its customers pursuant to 35 U.S.C. § 271 to directly infringe one or more claims of the '111 Patent, including Claims 1-7 of the '111 Patent, by intentionally promoting, aiding, and instructing customers to purchase and use systems and devices in a manner that incorporates the method claimed in the '111 Patent.

60. Defendant knew or should have known that the use of the systems and devices in a manner that incorporates the method claimed in the '111 Patent by its customers directly infringes one or more claims of the '111 Patent, including Claims 1-7 of the '111 Patent. Direct infringement by Defendant's customers is evidenced by statements on its customers' websites, for example, as shown in the claim charts attached to this Second Amended Complaint.

COUNT III

INFRINGEMENT OF UNITED STATES PATENT NO. 8,465,408

61. Wave incorporates the allegations of paragraphs 1-47 as if set forth here.

62. On June 18, 2013, the U.S. Patent and Trademark Office duly and legally issued the '408 Patent.

63. At all relevant times, Wave or its predecessor-in-interest, NeoSync, has been the lawful owner of right, title, and interest in and to the '408 Patent, including the right to sue for and collect past damages.

64. The '408 Patent is valid and enforceable.

65. As demonstrated by the claim chart attached as Exhibit 5, Defendant has been and is directly infringing pursuant 35 U.S.C. § 271, literally or under the doctrine of equivalents, one or more claims of the '408 Patent, including Claims 12, 20, and 21 of the '408 Patent by making, using, manufacturing, importing, offering for sale, and/or selling systems that incorporate the device claimed in the '408 Patent.

66. As demonstrated by the claim chart attached as Exhibit 5, Defendant has also been inducing, and continues to induce, its customers pursuant to 35 U.S.C. § 271 to directly infringe one or more claims of the '408 Patent, including Claims 1-4, 9-12, and 20-21 of the '408 Patent, by intentionally promoting, aiding, and instructing customers to purchase and use systems and devices in a manner that incorporates the method claimed in Claims 1-4 and 9-11 of the '408 Patent and the device claimed in Claims 12, 20, and 21 of the '408 Patent.

67. Defendant knew or should have known that the use of the systems and devices in a manner that incorporates the method or the device claimed in the '408 Patent by its customers directly infringes one or more claims of the '408 Patent, including Claims 1-4, 9-12, and 20-21 of the '408 Patent. Direct infringement by Defendant's customers is evidenced by statements on its customers' websites, for example, as shown in the claim charts attached to this Second Amended Complaint.

COUNT IV

INFRINGEMENT OF UNITED STATES PATENT NO. 8,870,737

68. Wave incorporates the allegations of paragraphs 1-47 as if set forth here.

69. On October 28, 2014, the U.S. Patent and Trademark Office duly and legally issued the '737 Patent.

70. At all relevant times, Wave, or its predecessor-in-interest, NeoSync, has been the lawful owner of right, title, and interest in and to the '737 Patent, including the right to sue for and collect past damages.

71. The '737 Patent is valid and enforceable.

72. As demonstrated by the claim chart attached as Exhibit 5, Defendant has and continues to induce its customers to directly infringe one or more claims of the '737 Patent, including Claims 1-4 and 8-11 of the '737 Patent by intentionally promoting, aiding, and instructing customers to purchase and use systems and devices in a manner that incorporates the method claimed in the '737 Patent.

73. Defendant knew or should have known the use of the devices and systems in a manner that incorporates the method claimed in the '737 Patent by its customers directly infringes one or more claims of the '737 Patent, including Claims 1-4 and 8-11 of the '737 Patent. Direct infringement by Defendant's customers is evidenced by statements on its customers' websites, for example, as shown in the claim charts attached to this Second Amended Complaint.

PRAYER FOR RELIEF

WHEREFORE, Wave prays for relief against Defendant as follows:

1. A judgment that Defendant has directly infringed and is directly infringing the '490 Patent and the '408 Patent;
2. A judgment that Defendant has induced infringement of each of the Asserted Patents, and is actively inducing infringement of each of the Asserted Patents;
3. An award of damages adequate to compensate Plaintiff for the infringement that has occurred under 35 U.S.C. § 284, including with pre-judgment and post-judgment interest;
4. An award of treble damages for Defendant's willful infringement of the Asserted Patents pursuant to 35 U.S.C. § 284;
5. An accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court's decision regarding imposition of a compulsory ongoing royalty;

6. An order under 35 U.S.C. § 283 permanently enjoining Defendant from continuing to make, use, sell, and/or offer to sell the infringing products and services and from further inducing or contributing to the infringement of the Asserted Patents;
7. An award of attorneys' fees, expenses, and costs based on this being an exceptional case under 35 U.S.C. § 285, including prejudgment interest on such fees, expenses and costs;
8. Costs and expenses in this action;
9. Such other further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues triable by jury.

Dated: October 13, 2023

Respectfully submitted,

/s/ Harry L. Gillam, Jr.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on October 13, 2023.

/s/ Harry L. Gillam, Jr.
Harry L. Gillam, Jr.